REMARKS

Claims 1-7, 9-17, and 19 are pending in the application. No amendments are presented with this response. In view of the remarks below, favorable reconsideration of the application is respectfully requested.

Applicants appreciate the courtesy of the telephonic interview extended by the Examiner to Applicants' undersigned representative on October 18, 2004. During the interview, the undersigned described the prosecution history to date, pointing out Applicants' concern at having taken steps to first remove the Lindstrom patent and then the Richmond patent and yet finding that Lindstrom was now reintroduced to reject the claims under section 102. There have been four office actions to date and progress was made to address each new rejection in turn.

During the interview, the Examiner stated that the PTO may have made a mistake in deciding that Applicants' remarks and amendments of July 29, 2002 overcame the initial rejection based on Lindstrom. She recommended that Applicants file the current response and present arguments explaining why the claim language, and particularly the "consisting essentially of" transitional language distinguished the Lindstrom reference and its recitation of certain required components. The Examiner also agreed to have a member of the USPTO's "quality review" group evaluate the response and determine whether the claims should be allowed.

Given the posture of the present prosecution, Applicants respectfully request that, should the Examiner determine that the application is still not in condition for allowance after reviewing this response, she contact the undersigned to discuss a future course of action before issuing another written action.

I. REJECTIONS OF CLAIMS 1-7 AND 9-18 UNDER 35 U.S.C. § 102(b)

Claims 1-7 and 9-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,725,586 to Lindstrom et al. ("Lindstrom"). Applicants respectfully traverse.

The claims as presented pertain to compositions that do not include material amounts of chondroitin sulfate or 2-mercaptoethanol. However, these components are essential to the functioning of Lindstrom's composition. Further, their presence, in functionally active amounts, would materially alter the basic and novel characteristics of the solutions recited in the pending claims.

The pending claims recite aqueous solutions *consisting essentially of* a source of bicarbonate ions, an organic zwitterionic buffer, and optionally a source of phosphate ions and/or a source of electrolytes selected from Na^+, K^+, Ca^{2+} and Cl^-. As explained in the background section of the present application, these solutions are simpler to use and more stable than those of the prior art BSS plus solutions. Therefore, a goal of the invention is to provide a simple and inexpensive, yet effective, optical irrigation solution. The presence of chondroitin sulfate and 2-mercaptoethanol, as required by Lindstrom, would add unnecessary expense and complexity to Applicant's solution.

Throughout the specification of the present application, advantages of the invention are indicated to include the absence of various components considered essential in prior art ocular irrigation solutions. Thus, a basic feature of the claimed invention is use of a simple solution free of unnecessary extra components that add expense, might not withstand sterilization by autoclaving, or could degrade over time. This feature is explicitly claimed by use of the "consisting essentially of" transitional language when characterizing the solution. See MPEP 2111.03. The working examples in the present invention further support this feature.

As explained in the Lindstrom patent, chondroitin sulfate and 2-mercaptoethanol have a direct impact on the functioning of Lindstrom's solution. See column 3, lines 49-50 and column 3, lines 30-32. Applicant's functionally effective solution, as claimed, does not require either of these compounds. In addition to introducing unnecessary expense, these compounds could, under the right circumstances, introduce unwelcome effects. For example, the 2-mercaptoethanol could be expected to degrade in potency when autoclaved to sterilize the solution. Because the claimed invention excludes compositions having active amounts of these compounds and because solutions employed in this invention would be materially changed by active amounts of these compounds, the claims are patentable over Lindstrom.

As explained earlier in Applicants' response of July 29, 2002, the surgical solution of Lindstrom is defined in claim 1 of the patent as follows:

"A composition for irrigating of flushing body tissue during surgical procedures, which composition comprises effective amounts of:

a. balanced salt solution comprising sodium chloride, potassium chloride, a sodium phosphate buffer system, calcium chloride, and magnesium chloride, the solution having a pH of about 7.4;

b. chondroitin sulfate;

c. a buffer system based on N'-2-2hydroxyethylpiperazine-N'-ethane sulfonic acid;

d. 2-mercaptoethanol;

e. sodium bicarbonate or dextrose;

f. a pyruvate;

g. a sodium phosphate buffer system; and,

h. cystine."

Claim 2 of Lindstrom recites a composition according to claim 1, but lacking components e, f, g, and h. This results in a composition comprising components a, b, c and d, namely a source of electrolytes in the form of a balanced salt solution, chondroitin sulfate, HEPES buffer, and 2-mercaptoethanol. This appears to represent the most basic composition of Lindstrom.

As explained, the irrigating solution of the pending claims is limited to essential features recited in the claim, namely a source of bicarbonate ions, an organic zwitterionic buffer, and optionally sources of phosphate ions and/or electrolytes. It does not contain material amounts of either chondroitin sulfate or 2-mercaptoethanol. By contrast, Lindstrom's most fundamental composition, that recited in claim 2 of Lindstrom, includes as essential components a balanced salt solution, chondroitin sulfate, HEPES buffer and 2-mercaptoethanol (see components a, b, c and d above).

In the surgical solution of Lindstrom, 2-mercaptoethanol is included in the solution to provide a reducing agent:

"*...2-mercaptoethanol is an effective reducing agent that can be utilized by human corneal endothelial cells.*" (column 3, lines 30 to 32 of Lindstrom) and is necessary for the functioning of the Na+-K+-ATPase pump of the endothelial cells:

"*...The Na+-K+-ATPase pump of these endothelial cells requires ATP and reduced pump sites to keep this pump functional. When the pumping action of these corneal epithelial cells is reduced, the cornea imbibes fluids and becomes thickened and looses optical clarity. Therefore, an irrigation solution with a reducing agent is of considerable advantage.*" (column 3, lines 12 to 18 of Lindstrom).

However, the irrigating solution of the present invention does not include 2-mercaptoethanol, yet still functions as an effective irrigating solution and is capable of supporting corneal endothelial function, as demonstrated in Example 1 of the present application, in which the irrigating solution of the present invention demonstrates a similarity in the rate of change of corneal thickness when compared with corneas exposed to BSS Plus.

The chondroitin sulfate which is included in the surgical solution of Lindstrom is a "*highly negatively charged glycosaminoglycan*" (see column 3, lines 40 to 41 of Lindstrom) and is "*added to replace any glycosaminoglycan that may be removed from the surface of the corneal endothelial cells from the disruption of aqueous flow or surgical trauma*" (see column 3, lines 40 to 44 of Lindstrom). However, the irrigating solution of the present invention is capable of supporting corneal endothelial cell function, despite the absence of chondroitin sulfate as a

component of the solution. Once again, the Examiner is referred to Example 1 on pages 6 to 9 of the present application.

It is also worth noting that Lindstrom does not itself mention autoclaving. While the broadest pending claims of the present invention do not require autoclaving, the ability to autoclave a solution is an important advantage of the invention. It is surprising that Lindstrom does not mention autoclaving since one might expect that if Lindstrom's solution were autoclavable, this would have been mentioned, especially given that Lindstrom et al. characterize their composition as an improvement over the BSS Plus solution which is sterilized by autoclaving.

In summary, 2-mercaptoethanol and chondroitin sulfate are essential Lindstrom. They are not part of the presently claimed invention. As explained, they would materially change claimed invention, both in terms of added expense and added complexity, which could introduce undesirable interactions. It is well known that claims employing the "consisting essentially of" transitional language are interpreted to cover compositions that include only the recited compounds as active components. In present case, chondroitin sulfate and 2-mercaptoethanol can only be viewed as active components based on their roles in the Lindstrom patent.

Withdrawal of the rejections is respectfully requested.

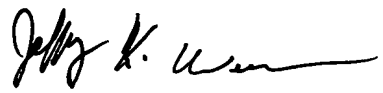
II. REJECTION OF CLAIM 19 UNDER 35 U.S.C. § 103

Claim 19 stands rejected under 35 U.S.C. § 103 as being obvious over Lindstrom in view of U.S. Patent No. 5,403,841 to Lang et al. ("Lang"). Lang discloses no composition meeting the requirements of the pending claims. Lang does not, therefore, overcome the deficiencies of Lindstrom and does not preclude patentability of claim 19 or any other pending claim.

III. CONCLUSION

Applicants believe that all pending claims are in condition for allowance, and respectfully request a Notice of Allowance at an early date. The Examiner is encouraged to contact the undersigned at the telephone number below if any issues remain.

Respectfully submitted,
BEYER WEAVER & THOMAS, LLP



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